

Informed Consent Form about the Clinical Study

Lay Title:	A study to test vicadrostat (BI 690517) taken together with empagliflozin in people with type 2 diabetes, high blood pressure, and cardiovascular disease
Protocol Title:	A Phase III double-blind, randomised, parallel-group superiority trial to evaluate efficacy and safety of the combined use of oral vicadrostat (BI 690517) and empagliflozin compared with placebo and empagliflozin in participants with type 2 diabetes, hypertension and established cardiovascular disease
Protocol Number:	1378-0041
Participant Number:	
Sponsor:	Boehringer Ingelheim Pty Limited Dr. Andrew McCann
Study Doctor:	Life Clinical Research - 33 Thorn Street, Ipswich QLD Ph: 0734490036

You are being invited to take part in a clinical research study because you have been diagnosed with type 2 diabetes, high blood pressure and cardiovascular disease. The information in this document should help you to decide if you would like to participate. Your participation in this study is voluntary. Your condition may or may not improve if you decide to participate in the study. But the information we get from this study might help other people with the same condition in the future. Your decision will not affect your future medical care.

The study staff will explain the purpose of the study and the possible benefits and risks of your participation. Please ask questions about anything that is unclear at any time. Take your time to decide. Feel free to discuss with your family, friends, or personal doctor.

If you decide to participate, you will be asked to sign a form called 'Consent to participate in the study'. After that, your participation in the study starts. It is important that your personal GP and specialist(s) are aware that you are in a research study because you may be taking a treatment that could affect your health. With your permission, your study doctor will notify them. Please keep in mind, you can withdraw from the study at any time without any negative effect on your regular medical care.

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the [National Statement on Ethical Conduct in Human Research \(2023\)](#). This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may



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contact the Operations Manager, Bellberry Limited on 08 8361 3222.

You will receive a copy of this signed information and consent form for your records.



Short overview

This study is to find out whether a medicine called vicadrostat when used with another medicine called empagliflozin helps people with type 2 diabetes, high blood pressure and cardiovascular disease.

This study compares vicadrostat (also known as is BI690517) plus empagliflozin with a placebo that matches vicadrostat plus empagliflozin. A placebo looks like the vicadrostat tablet but does not contain any active medicine.

You will have an equal chance to receive either the vicadrostat 10 mg (1 tablet) plus empagliflozin 10 mg (1 tablet) or the vicadrostat placebo (1 tablet) plus empagliflozin 10 mg (1 tablet). It will be decided by chance (like flipping a coin) which treatment you will receive. Both the vicadrostat (or placebo) and empagliflozin will be provided to you in tablet form. You will take 1 tablet of vicadrostat (or placebo) and 1 tablet of empagliflozin once per day. Neither you nor the study doctor will know if you are taking the vicadrostat or the placebo.

The duration of your participation in this study will depend on when you join the study. This means that there is no fixed total duration for each participant but rather the study will end for everyone at the same time, no matter when you entered the study. Depending on when you join, your participation may last for around 2.5 years or could be up to 4.25 years. The number of visits that you will attend will depend on how long you participate in this study. During the first year, you will attend up to 5 visits and receive 3 phone calls. After the first year, there will be 2 visits and 2 phone calls per year. These phone calls and visits will occur approximately 3 months apart and alternate so that you will receive a call, then go to the site, then receive a call and then have another clinic visit.

At the visits, your study doctor will assess your health by doing some routine assessments. Your study doctor will ask you how you have been feeling and if you have had any changes to your health (e.g. new diagnosis or needed to go to the hospital for any conditions like a heart attack, stroke, or for the development of heart failure). The results will be compared between groups of participants to see whether the treatment works. The study doctor will regularly check your health and record of any unwanted effects. Unwanted effects are any health problems that the doctors think may have been caused by the investigational product or treatment.



Please carefully continue reading the following pages that inform you about the study. While reading you will be referred to the [Sections A](#) to [E](#) where you can find further information.



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1. What is this study about?

The purpose of this study is to find out whether a new medication helps reduce the development of serious health conditions. To do this, we will collect data about cardiovascular events (e.g. development of heart failure, heart attack or stroke, etc.) that happens to people during this study. After enough data on the cardiovascular events has been collected in the study, we will be able to find out if the investigational product reduces the number of cardiovascular events that people may develop.

What is the investigational product?

There are two different investigational products that will be used in combination in this study.

Vicadrostat is being developed to treat people with cardiovascular disease (heart and blood vessel problems) who also have type 2 diabetes and high blood pressure. Vicadrostat has not been approved as a treatment for any disease in any country. Thus, its use in this clinical study is experimental.

Empagliflozin has been approved for use in Australia for the treatment of type 2 diabetes as well as to reduce the risk of cardiovascular death in adults with type 2 diabetes and cardiovascular disease.

How will this study be done?

This study compares vicadrostat with placebo when taken with empagliflozin along with the medications or treatments that you take for type 2 diabetes, high blood pressure and cardiovascular disease. A placebo is a substance that looks like the investigational product but contains no active drug. All patients will receive empagliflozin.

It will be decided by chance which treatment you will receive. This is called randomization.

You will have an equal chance of getting one of the following treatments:

Group A: Vicadrostat plus empagliflozin

Group B: Placebo (vicadrostat) plus empagliflozin

You will not know which investigational product you are getting; the study doctor and study staff will not know either. This way the results of the study will not be favoured one way or another. If it becomes necessary for your care, your study doctor will be able to find out which investigational product you are taking.

After the study ends, you can ask to find out which investigational product you received. This may not be possible until several months after your last study visit.

How many people will take part in the study?

Approximately 11,800 people will participate worldwide, 375 will participate from Australia and up to 20 will participate at Life Clinical Research.



2. What will happen if I participate in this study?

This section summarises what you can expect during visits for this clinical study.



You can find out in detail what will happen at each visit and how long each visit will take in [Section A](#). The tests and checks done at the visits are described in [Section B](#). Your study doctor and the study staff will go through these details with you.

Screening visit (Visit 1)

Before you get the investigational product, you will attend a screening visit. At this visit, the study staff will perform screening tests, including a physical exam and confirm your study eligibility. If the results of the screening tests show that you cannot participate this time, you may be able to participate in another study in the future. You are not permitted to be screened at another study site for this study. Keep in mind, the tests are done to check if it is safe for you to take part in the study.

Baseline visit (Visit 2)

At this visit, the study staff will do additional screening tests, including a physical exam and checks to confirm that you can safely participate in this study. Once your eligibility is confirmed, you will receive the investigational product. This visit may also be called the randomization visit. Randomization means that you are put into one of two possible treatment groups by chance.

Your study doctor will give you the investigational product to take home. You will be trained how to take the investigational product.

Regular visits during treatment

For 2.5 – 4.25 years, you will take the 1 tablet of vicadrostat (or placebo) and 1 tablet of empagliflozin once daily. During this time, you will attend regular study visits, where site staff will monitor you for any effects of the investigational product, and these effects will be recorded. Some visits will take place at the study site and some visits the site staff will call you on the telephone.

At each visit, the study doctors will take note of any changes to your health and collect information on any health problems. Your study doctor may want to see you or contact you by phone more frequently than what is described above and outlined in Appendix A below. Some reasons for the additional visits include additional follow-up if there are any changes in your health or lab tests that may need to be repeated sooner than the next scheduled visit. There could be other reasons for an additional visit, but the study doctor or site staff will explain why you may need to have an additional visit.

During the study, for exceptional circumstances and in agreement with you and the site staff, your study doctor may arrange to send the investigational product directly to your home. More information about this service is provided in a separate informed consent that the site staff will provide to you.



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End-of-treatment visit

After enough data on the cardiovascular events have been recorded in the study, you will be asked to return to the study site for an end-of-treatment visit. Or if it is decided that you will stop taking the vicadrostal (or placebo) ahead of schedule, you will need to attend an end-of-treatment visit. At this visit you will have the same type of assessments that were done before. As before, a physical exam will also be done to check your general health. Your study doctor will discuss your future care with you.

Follow-up period and follow-up visit

After you stop taking the investigational product, you will remain in the study for one additional week. This is called the follow-up period and is important for your safety. Any changes to your health that continue after the treatment will be followed until the study doctor considers this health change resolved. At the end of this period, you will attend the end of study visit. This will be your last visit in this study. If you stopped taking the investigational product ahead of schedule, you will be asked to come for the end of study visit after enough data on cardiovascular events has been collected.

What are my responsibilities as a study participant?

If you decide to participate in the study, we ask you to follow a few rules. This is to protect your safety and to make sure the study results are valid.

- Follow the instructions provided by the study staff. Come to all scheduled study visits and be available for any scheduled visits at home (e.g., phone calls).
- Do not participate in another clinical study or in this clinical study at another site. You may harm yourself if you participate at multiple sites.
- Tell the study doctor if you have participated in a clinical study within the last year.
- Tell the study doctor if you observe any change to your health. For example, you may feel unwell or feel better. Share any effects on your health, even if you think they have nothing to do with this study.
- Tell the study doctor about all prescription and non-prescription medicines, herbal preparations, and food supplements that you are taking or planning to take. There may be some foods and medicines that you should avoid while in this study because they may interact with the investigational product or could affect the study results. Your study doctor will tell you which ones.
- You should avoid exercise, smoking, and caffeine at least 30 minutes before having your blood pressure measured during the study visits.
- Always carry the 'Trial Identification Card' with you. This card has information on the study and contact details. Show this card to any doctor who may treat you, for instance, in an emergency.
- Inform the study site staff of your current address and telephone number. If you move or change your telephone number, please inform the site staff. The site staff will ask you to provide an emergency contact person. This could be a spouse, family member, friend or neighbour. If the site staff are unable to contact you, they may reach out to your emergency contact person to find out if you are alright.
- Tell the study staff if you are treated by another doctor during this study. It is important that they understand what happened.



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- You must come to the study site early in the morning, within four hours from waking up, on the days for Visit 3 and Visit 5. During these visits, cortisol blood samples will be collected.
- Take and store the investigational product as instructed.
- Use the investigational product only for yourself as instructed.
- Do not use the investigational product for any other purpose.
- Remember to bring your unused investigational product and all empty containers to each of your study visits. Explain if there is any lost or missing investigational product.

Do I have to pay to participate in the study?

Some of the tests or treatments used in this study may be part of standard care used to maintain your health even if you did not take part in the study. You will be responsible for the cost of any tests or treatments that are considered standard care in the usual way (health insurance, Medicare and your personal contribution depending on your circumstances). All study-related tests and treatments will be provided at no cost to you. You should ask the study doctor to explain any payments for which you may be responsible.

Will I be reimbursed for expenses?

Yes, you will be compensated to cover out-of-pocket expenses such as transportation, parking, meals and your participation in the study.

You will also receive a payment for completing study visits.

For each visit where you attend the clinic in-person, you will be provided a reimbursement of \$80 to cover any mileage, parking, public transport or taxi expenses.

Reimbursement for out-of-pocket expenses and your visit completion payment may be provided by a company called Scout Clinical, should you agree. In addition, depending on your travel distance to and from the study site, you or the study staff may be able to book certain means of travel through a travel agency if needed. The use of the travel services will be provided at no cost to you, should you agree to use them. The site staff will provide you with further information about the reimbursements, study payment for completing the study visit, and use of the travel services, as well as an additional consent form to review and sign if you wish to use them. You may also choose to be paid directly by the site to your nominated bank account. The amounts will be the same as if you were paid by Scout.

You will receive visit completion payments of up to \$125 AUD for participating in each study visit. The amount paid will vary depending on the type of visit (clinic or phone) and how long you are required to attend each visit. Your study coordinator can provide you with a list of how long each visit is expected to take and how much you will be compensated accordingly.

Is the study doctor paid to conduct this study?

Yes, the sponsor pays the study doctor, the institution, and service providers for their expenses, time, and effort to conduct this study.



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What happens if there is new information during the clinical study?

We will let you know in a timely manner if there are changes to study procedures, newly discovered side effects, or important findings which may affect your health or willingness to continue to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this study.

What happens if something is found out in research that is important for study participants?

There is a small chance that researchers discover new information outside this clinical study that might be important to your health or medical care. These are called incidental findings. If this happens, we will use reasonable efforts to inform your study doctor, who can discuss further options with you. Please let your study doctor know whether you would like to be informed about such new information.

3. What are the benefits of participating in the study?

Your participation in this clinical study helps doctors and researchers find medicines for others in the future. You may not personally benefit from participating in this study. But you may benefit from the additional care and attention from the study staff.

4. What are the risks of participating in the study?

Any medical procedure, treatment and therefore any clinical study has risks. Your condition might not improve, or it could get worse during the study.

Please be aware that, depending on your treatment allocation, you may receive placebo that looks like vicadrostat but does not contain any medicine. Regardless of that, you will receive empagliflozin.

The study doctor and the study staff will monitor your safety carefully. The investigational product may be stopped or paused any time if any safety issues are noted.

There is a potential risk of breach of privacy associated with any unauthorized release of personal information. Further information can be found in [Section E](#).

What are the medical procedures in this clinical study?

Medical procedures of this study and their risks are described in [Section B](#).

What are the possible side effects of the investigational product?

If you receive the investigational product, side effects may occur. Many side effects can be treated. Some may go away when you stop taking the investigational product. Others may continue or become permanent.

As with any medicine, an allergic reaction can occur. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or breathing difficulties. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing, call **000**.



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Side effects, including allergic reactions may be mild, but some may be life-threatening or fatal. Possible side effects for the investigational product are provided in [Section C](#). The study doctor or the study staff will go through these with you. Ask any questions you might have.



There is also a risk of having effects on your health that are not yet known. Tell your study doctor or the study staff as soon as possible if you observe any change to your health.

Some effects on your health may occur during or after you have left the study. Your health will be monitored throughout the study. If the effects on your health seem related to your participation, the study doctor will inform the sponsor.

Pregnancy



If you can have children and are sexually active, please read this section, [Section C](#), and [Section D](#) carefully before choosing to participate in this study.

If you can become pregnant, you may take part in this study only if you use a highly effective form of birth control. However, no one method of contraception is 100% effective. If you are a woman who is breastfeeding, pregnant, or you plan to become pregnant during the study, you may not take part in this study. We do not know how vicadostat and empagliflozin may affect the growth and development of your unborn baby.

You can take part in this study without pregnancy tests or birth control if you are unable to become pregnant, because you are someone without a uterus or any ovaries, someone who had both of their uterine tubes removed, someone who does not have sex with partners who produce sperm, or someone who has been through menopause. You have been through menopause if you had no period for at least 12 months and this was not caused by another medical reason.

For men, birth control is not required during this study.

5. What happens if I decide not to participate in this study?

Instead of participating in this study, you might have other options.

You may receive treatments that are approved for the treatment of type 2 diabetes, high blood pressure and for cardiovascular disease. Or you may also take part in another clinical study.

Your study doctor will discuss these options with you and explain potential risks and benefits. This will happen before you decide to participate in this study.



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What if I change my mind about participating in the study?

You can change your mind at any time. It is important that you tell the study doctor if you want to stop. In this case, the doctor can evaluate the risks of stopping the vicadrostat (or placebo) and/or empagliflozin. In some cases, sudden stopping of the investigational product can have risks, which the study doctor will explain. There is no penalty for leaving the study early. You also do not have to give a reason. Leaving the study will not affect your future medical care.

Even if you do not want to take the investigational product anymore, it is important that the study staff can continue collecting data about your health. This is to make sure that the results of the clinical study are valid. This means you may stop taking the investigational product but continue participating in the study. In such a case, you will still come for study visits, or the study staff will contact you to ask about your health.

You can stop taking the vicadrostat (or placebo) and continue to receive the empagliflozin until the end of the study. Or you can stop taking both the vicadrostat (or placebo) and the empagliflozin and continue to participate in the study. Your participation will be adjusted to best suit your needs. The following options for continued participation are possible. Your study doctor will discuss these scenarios with you.

- Option 1: you may continue to attend visits as outlined in Appendix A while not taking the investigational product.
- Option 2: you may continue to participate in the study but have remote visits (e.g. phone calls instead of going to the study site)
- Option 3: you may come to the site or be contacted by phone periodically to fit with your schedule. Hopefully you will go to the clinic or have a phone call once per year or at a minimum once before the study ends.
- Option 4: you or your designated person may be contacted when the study is ending.
- Option 5: If you do not want to continue with the study visits or to be contacted by the study staff, then we will ask for your permission to collect relevant information from your medical records or any public records at the end of the study.

A patient locator service may be used. More information about this service is provided in a separate informed consent that the site staff will provide to you.

This information is important for the scientific value of the study to interpret the study results correctly. You are free to refuse this regular contact or change your option for follow-up at any time.

You may re-start the investigational product at any time when the study is still ongoing as long as your study doctor has confirmed that it is safe for you to re-start the investigational product.

You may also withdraw from study participation completely. In this instance, please tell the study staff that you want to withdraw from all future visits and contacts. You will then no longer attend visits and the study staff will not contact you anymore. No additional data about you will be collected.



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Data and lab samples (blood and urine) that were collected about you and from you before the time of withdrawal will still be used in the analysis of study results. If you prefer that not yet analysed lab samples collected before your withdrawal are destroyed, you must inform your doctor. Your study doctor may also decide that you should stop taking the investigational product if they think this is best for your health. The sponsor or the regulatory authority may also decide to discontinue the study. Such decisions would not need your consent. If you are removed from the study, the study doctor will explain to you why you were removed.

6. What else is important to know?

Can I provide feedback on my study experience?

Yes, you can fill in the study participant questionnaire that will be shared with you at the beginning, middle and end of your study participation. This helps us to learn from your experience as a study participant. Please note, this questionnaire is optional, so you do not have to do it. The questionnaire will ask for your consent before you complete the questions. Your decision to participate in this study is not dependent on your decision to complete the questionnaire.

What happens if I am injured during the study?

If you are injured as a result of your participation in this trial, you may be entitled to compensation. There are two avenues that may be available to you to seek compensation.

- 1) Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia, will govern the way in which compensation claims from injured participants are managed by sponsors.

However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines.

These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au) under Policy – Clinical Trials – Indemnity and Compensation Guidelines. Alternatively, your study doctor can provide you with a hard copy of the guidelines.

- 2) You may be able to seek compensation through the courts.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.



7. Who to contact in case of emergency or questions?

The person you may need to contact will depend on the nature of your query.



In case of an emergency, call 000.



If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor on 07 3449 0036 or any of the following people:

Clinical contact person

Name	Dr. Andrew McCann
Position	Medical Director – Life Clinical Research
Telephone	07 3449 0036
Email	Andrew@LCR.Health

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Paul Christensen
Position	Clinical Operations Director – Life Clinical Research
Telephone	0417 108 585
Email	Paul@LCR.Health

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Bellberry Human Research Ethics Committee
HREC Executive Officer	Director of Operations
Telephone	08 83613222
Email	bellberry@bellberry.com.au



A: Visit schedule

On the next page is a chart showing your visit schedule. The pictures in the chart show what happens at each of your visits. Please refer to the picture guide on this page while viewing the visit schedule.

Locations and visits		Consent, training, and assessing changes in your health		Procedures performed	
	At the study site		You give your consent to enter the study.		Your body weight is measured. At the Screening visit your height will be measured.
	At home (video call or phone call)		Demographic data including your age/birth year, gender identity, sex, race and ethnicity will be recorded		Your blood pressure and pulse rate will be measured.
	Approximate duration of visit		Your medical history is recorded		A physical exam will be performed on you.
Visit 1	Screening visit		Review of medications or treatments you may be taking or receiving		An electrocardiogram is performed on you.
	Morning Visit to occur within 4 hours of waking up		Starting at visit 1 you will be assessed for any changes in your health or asked how you are feeling.		Blood and urine samples are collected. If you are able to become pregnant, a pregnancy test will be performed.
Visit 2	Randomization visit		You will receive the investigational product and instructions on how to take.		
Visits 3-23	Regular visits		Please bring back the unused investigational product and empty packaging.		
EoT (or early EoT)	End of treatment visit		The study feature or procedure represented by the icon occurs during that visit.		
EoS	End of study visit				

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Visit #	Week #	Location													
1	-1 to -3 wks		2:30 – 3:30 hrs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
2	1 wk		1:30 – 2:30 hrs				✓	✓	✓	✓	✓	✓	✓	✓	
3	3 wks		1:00 – 2:00 hrs				✓	✓	✓	✓		✓	✓		✓
4	8 wks		15 – 30 min				✓	✓							
5	12 wks		1:30 – 2:30 hrs				✓	✓		✓	✓	✓	✓	✓	✓
6	18 wks		15 – 30 min				✓	✓							
7, 9, 11, 13, 15, 17, 19, 21, 23	24 wks then repeat every 24 wks		1:30 – 2:30 hrs				✓	✓	✓	✓	✓	✓	✓	✓	✓
8, 10, 12, 14, 16, 18, 20, 22	36 wks then repeat every 24 wks		15 – 30 min				✓	✓							
EoT (or Early EoT)	TBD*		1:30 – 2:30 hrs				✓	✓	✓	✓	✓	✓	✓	✓	✓
EoS	EoT + 7 days		1:00 – 2:00 hrs				✓	✓	✓	✓		✓	✓		✓

* TBD = to be determined

Study No: 1378-0041

Life Clinical Research Main ICF V1.0 dated 05Aug2025 based on
Bellberry Main Participant Information and Consent Form V2.0 dated 30Jun2025

IQVIA Version and for Sponsor Use Only:

Main_V1.0AUS1.0Bellberry2.0_022v1.0(05Aug2025)



B: Study procedures and risks

To conduct the study, the procedures listed below will be performed. The study staff will describe them to you and explain any risks. Please read about the procedures carefully and ask any questions you might have.

	Vital signs These include the recording of your pulse rate (or heart rate) and blood pressure. You will be asked to sit and relax for about 5 minutes. Then your blood pressure will be measured three times with about 1 to 2 minutes between each measurement. These tests are painless and have little risk.
	Blood sampling A sample of your blood will be collected to check your general health. These samples will be discarded after the analysis is complete. The study staff uses a small needle to take blood from your arm or hand. The blood is collected into a tube. This usually takes less than five minutes. At each clinic visit, about 15 mL (about 1 tablespoon) of your blood will be drawn. Over your entire time in the study, if you participate for 4.25 years then about 207 mL blood will be drawn. This is less than 1 cup. If your study doctor wants to re-check any blood tests, the amount of blood drawn will be more. The risks of having your blood sampled include: • redness, swelling, a bruise, and/or infection at the needle insertion site • dizziness and/or nausea • fainting • in very rare cases, nerves may be damaged at the puncture site, including long-lasting abnormal sensations (paresthesia). Urine sampling A sample of your urine will be collected. You will be asked to collect a “mid-stream” sample which means that you only collect the middle part of the flow of urine and not the first or last part. Because this procedure involves normal urination, there should not be any discomfort and no known risks. Pregnancy test If you are able to become pregnant, a pregnancy test will be performed. This test measures a hormone in the body called human chorionic gonadotropin (HCG). This hormone is present in your body when you are pregnant. A pregnancy test is done using your blood or your urine. You cannot participate in a clinical study if you are pregnant or planning to become pregnant. Pregnancy tests using blood: risks are the same as with all blood sampling.



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	Pregnancy tests using urine: there should not be any discomfort and no known risks because this procedure involves normal urination.
	ECG (electrocardiogram) An ECG checks the health of the heart by measuring your heart's electrical activity. For an ECG, electrodes with sticky pads are placed on the skin on your chest and other parts of the body (like arms or legs). The electrical activity of your heart is viewed on a monitor. An ECG is a painless and safe procedure. There may be minor irritation to the skin after removing the sticky pads.
	Physical examination A routine examination that your study doctor will perform to check your overall health. This examination generally produces little pain or discomfort.
	Weight and height measurement Height is only measured at the Screening visit. You should remove your shoes and any headgear (e.g. hats) before having your height measured. Headgear worn for religious reasons are acceptable. Body weight will be measured with an empty bladder. You should remove your shoes, coat or jacket and empty pockets of heavy objects (e.g. keys, coins, etc.) and remove any headgear before your weight is measured. If headgear is worn for religious reasons, this should be consistently worn for all weight measurements in the study. Measuring your height and weight are routine procedures with little risk.



C: Possible side effects of the investigational product

Your study doctor will closely look for any changes to your health that happen while you take part in this study.

- Taking any medicine has risks. Taking the investigational product vicadrostat and empagliflozin may cause you to have one or more possible side effects listed below.
- Possible side effects are changes to your health that may be caused by the investigational product.
- The study doctor or staff will go through descriptions of the possible side effects with you. Ask any questions you may have.
- If any side effects happen, the study doctor will assess your condition and discuss options with you.
- Tell the study doctors or staff if you have any changes to your health while taking part in this study. This is important even if you don't think it was caused by the investigational product.
- In addition to the side effects listed for vicadrostat and empagliflozin, there is always the risk of developing side effects which are not known at this time.
- We do not know which side effects may occur from taking the combination of vicadrostat and empagliflozin.

Please carefully continue reading the following pages that inform you about the risks.

Possible side effects of vicadrostat

A possible side effect identified in a study in people with diabetic or non-diabetic chronic kidney disease is having too much potassium in the blood (hyperkalaemia). Your potassium levels will be monitored closely during the study. If you are found to have high potassium levels in the blood, the study site staff may adjust your treatment or give you additional medication to help manage this. Potassium levels in the blood are closely related to your kidney function.

Dehydration can reduce kidney function. Therefore, it is important that you:

- drink enough (water), especially during hot weather
- contact your study doctor if you feel you are urinating less than usual.

Are there any other risks of vicadrostat?

There may be other risks of taking vicadrostat that we do not know. This can include risks found when taking medicines similar to vicadrostat. These risks include insomnia, dizziness, fainting (syncope), headache, heart rate that is too fast (tachycardia), irregular heartbeat (atrial fibrillation), low blood pressure (hypotension), cough, diarrhoea, nausea, difficulty to pass stool (constipation), vomiting, muscle spasms, back pain, decrease in kidney function (renal impairment), weakness (asthenia), change in blood test results including: increase in blood urea, creatinine and testosterone levels, or decrease in sodium levels in the blood (hyponatremia).



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Vicadrostat could affect a stress hormone called cortisol. Therefore, we will monitor for symptoms related to your cortisol levels during the study. Tell the study staff if you notice any of the following signs:

- Fatigue, nausea, low blood pressure, low blood sugar (this could be due to low cortisol levels)
- Easy bruising, redness and swelling of the face, stretch marks (this could be due to high cortisol levels)

Your study doctor may decide to check your cortisol levels.

Possible side effects of empagliflozin

Empagliflozin has been taken by more than 20,000 participants in clinical studies. It is an approved medicine for people with type 2 diabetes, people with heart failure, and people with CKD.

Empagliflozin helps your body get rid of excess sugar through urine. This helps control blood sugar levels. Empagliflozin also provides benefits for your heart and kidneys. Due to the way empagliflozin works, you may initially notice a need to pass urine more often. You may also experience signs of dehydration such as thirst or difficulty to pass stool.

Due to the increased sugar in the urine, the chance of getting a urinary tract or genital infection is increased. Serious urinary tract infections or genital infections that may lead to hospitalization have happened in people who are taking empagliflozin. Please contact your study doctor immediately if you feel pain, tenderness, redness, swelling of the genital area, or straining or pain when passing urine. Your study doctor will treat you.

In people with type 2 diabetes, there is the risk of low blood sugar (hypoglycaemia) if you take empagliflozin together with other treatments for your condition (sulphonylurea or insulin). Have a sugar drink if you have typical signs for low blood sugar including dizziness, sweating, shakiness, hunger, restlessness, slurred speech, or confusion.

If you are feeling sick, have stomach pain, shortness of breath, a sweet smell or metallic taste in your mouth, please contact your doctor. This may be a sign of increased levels of blood ketones (ketoacidosis). If your body doesn't have enough insulin, ketones can build up, and your blood sugar might be high or normal.

Ketoacidosis can occur if you eat very little, fast, wait for surgery, or are severely dehydrated from vomiting or diarrhoea. It's rare in people without diabetes but can be life-threatening if untreated. Stop taking the investigational product if you can't eat or drink, or have severe vomiting or diarrhoea, and contact your doctor immediately.

Some other side effects of empagliflozin can include skin itching, dehydration and abnormalities on blood and/or urine tests.

There may be other risks of taking empagliflozin that we do not know.



D: Acceptable methods of birth control



For female study participants

If you can become pregnant, you may take part in this study if you:



- Have a pregnancy test done before you take the investigational product, at study visits, and at the end of the study.
- Use **highly effective methods of birth control** (see below) during study participation and for at least 1 week after your last treatment with investigational product:
 - For participants using hormonal contraceptives, a supplemental barrier method (preferably male condom) should be used in addition to the hormonal contraceptive.

Your doctor will talk to you about the best method of birth control for you. If used correctly and started at least 2 weeks before you start taking the investigational product, **highly effective methods** of birth control are:



- Intrauterine device (IUD) or intrauterine hormone-releasing system
- Estrogen and progestogen containing hormonal birth control that prevents ovulation (taken as pills, inside the vagina, or skin patch).
- Progestogen-only hormonal birth control to prevent ovulation (taken as pills, inside the vagina, skin patch, injection, or implanted).

The following are also considered highly effective methods of birth control if you currently:

- Are a woman who has blocked tubes on both sides of the uterus (tubal occlusion)
- Have a male partner who is vasectomised, and the absence of sperm was documented.

If abstinence from male-female sex is a part of your regular sexual practice, you can participate in the study without taking birth control. **However, you should be aware that periodic abstinence is not an acceptable method of birth control.**

If you become pregnant or think you could be pregnant:



- Tell the study doctor or the study staff right away.
- You will stop taking the investigational product and be asked to continue with study visits.
- You will be asked to provide information about you and your baby. A separate Pregnancy Participant Information Sheet and Consent Form will be provided. This is optional, you do not have to agree to this follow-up.



For male study participants

For men, birth control is not required during this study.



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Informed Consent Form for Study Participants

E: My data

Protection of your personal information is very important to us. The study doctor, the study staff, and the sponsor will take all steps to make sure your data is safe.

What information about me is collected in the study?

The study doctor and the study staff will collect data

- like your name, age, address, and
- information about your health, for example medical records with results of medical tests or any unwanted effects.

The study doctor may ask you to sign a form that will allow the study doctor to request your regular doctor or a hospital to provide your medical records.

What is my data needed for?

Your data is needed by the sponsor to develop the investigational product, get permission to introduce and keep it on the market, monitor its safety, and get it covered by health insurances. Therefore, your data will be used as planned in this study and for other clinical development programmes to:

- understand how the investigational product and/or other medicines work in the body,
- better understand the health condition and/or other health problems,
- develop diagnostic tests and/or therapeutic products for the disease,
- learn from past studies to plan new studies and/or improve scientific analysis methods,
- publish research results in scientific journals and/or use them for educational purposes.

Who can see my data?

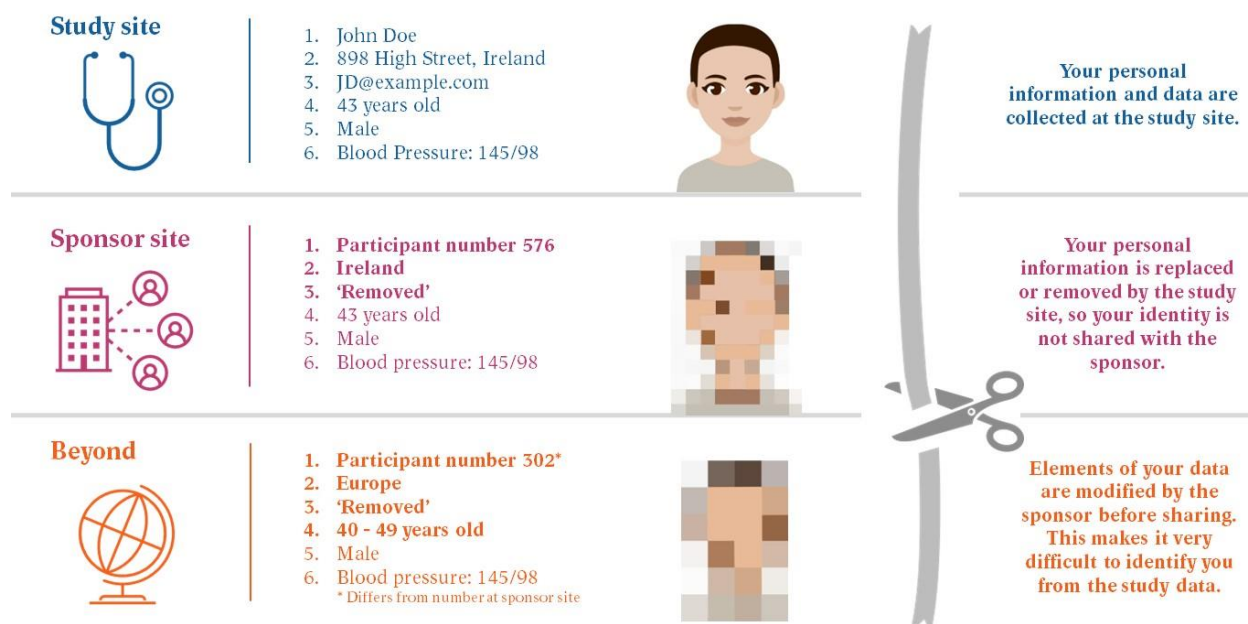
Your study doctor, the study staff, and other people assisting with the study and with your care can access your data, like your name and contact information. For example, medical personnel may come for a scheduled visit to your home, or non-medical personnel may deliver investigational product or devices to your home. Personnel acting on behalf of the sponsor or from health authorities may access participants' data to verify that the study is carried out in compliance with legal and quality requirements. This means that those people get direct access to your medical records to check that study procedures are correctly done. Such personnel include monitors, auditors, and representatives from Institutional Review Boards or Ethics Committees. Everyone involved is legally required to keep all personal information confidential.

The study site will share your data with the sponsor only after your name and contact details have been replaced by a code, for instance your name is replaced by a Participant Number. The following diagram shows how your personal data is protected before it is shared as coded data by the study site or by the sponsor site.



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Participants should note that, some data from your participation in this study will be sent overseas or shared with persons outside Australia. The regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. If you have any questions about this direct them to the Principal Investigator.

The sponsor will share coded data with its research partners and service providers (like clinical research organizations or laboratories) and companies belonging to the sponsor's group.

To make sure study results are accurate and to get permission to market the investigational product, the sponsor will also share coded data with regulatory authorities and possibly with Ethics Committees and reimbursement agencies. Coded data may also be shared with scientific journals so the study results can be reviewed to ensure accurate results. Your identity will not be revealed in any of these cases.

The people involved in data analysis and processing data in any other way may be located outside your country or outside of the European Union. If data protection standards are lower in this other country, appropriate safeguards (such as contracts and technical security measures) will be taken to protect data.

In case another organisation takes over development or commercialisation of the investigational product, coded data may be transferred to them. They will then have to protect data in the same way as described within this document.

Beyond, the sponsor may only share study data if they were anonymized. This means all information that could identify you were removed as shown in the diagram above. Such data can help to answer further medical questions.

Study No: 1378-0041

Life Clinical Research Main ICF V1.0 dated 05Aug2025 based on
Bellberry Main Participant Information and Consent Form V2.0 dated 30Jun2025

IQVIA Version and for Sponsor Use Only:
Main_V1.0AUS1.0Bellberry2.0_022v1.0(05Aug2025)



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Informed Consent Form for Study Participants

The sponsor's head office is in Europe and must comply with the European Union General Data Protection Regulation (GDPR). The GDPR gives you additional rights that may not be specified in your country's regulations.

You have the right to:

- review which of your data is collected and being used,
- restrict the processing and use of your data,
- object to the use of your data or to ask to have incorrect data corrected,
- ask the study doctor to provide you with a copy of your data in a standardised electronic format or to have them transmitted to another person of your choice,
- file a complaint with your local data protection authority or with the sponsor's European data protection authority at: Rhineland-Palatinate Officer for Data Protection and Freedom of Information, Hintere Bleiche 34, 55116 Mainz, poststelle@datenschutz.rlp.de.

Please keep in mind you will not be able to review some of the data or receive a copy of it until the study has completed worldwide.

If you wish to apply any of your data privacy rights, or have any questions, please inform the study doctor or the study site's Data Protection Officer Paul Christensen, privacy@LCR.Health, 0417 108 585..

How long will my coded data be kept?

Your coded data will remain at the study site and with the sponsor for a maximum of 30 years and then the link to your code will be destroyed by the study staff. After that it is not possible for anybody, including the study staff or sponsor, to link your data directly back to you.

Where can I find the study results?

The results of this clinical study will be publicly available. These results will not include information that could identify you. Results are only reported as summaries for groups of participants, not individually per participant. A description of this clinical trial will be available on <https://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

A description of this study and its results will also be available on the European Union (EU) website <https://euclinicaltrials.eu/home>, as required by the EU Clinical Trial Regulation.

The results of this study will be summarized in an easy-to-understand summary. You will be able to access this summary and a scientific summary on the sponsor's clinical studies website <https://www.mystudywindow.com/completed>.

The results may also be published in local clinical study registries of the participating countries.

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We are committed to publish results in scientific journals and share them at scientific meetings. Your identity will not be disclosed in any published results.

Can some data from this study also help to answer further medical questions?

Yes, researchers must specify the scientific or medical question in a written proposal and prove their credibility. An Independent Review Panel reviews this proposal. This Panel consists of a chairperson, a lay person, and experts in statistics, conducting clinical trials, ethics, and data governance. If the proposal has been approved by the Panel, the sponsor shares anonymized data collected in the study that may help to answer the raised questions.

It is in the best interest of patients and public health to advance medical knowledge and protect participants' privacy.



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Informed Consent Form for Study Participants

Consent to participate in the study:

Title: A Phase III double-blind, randomised, parallel-group superiority trial to evaluate efficacy and safety of the combined use of oral vicadrostat (BI 690517) and empagliflozin compared with placebo and empagliflozin in participants with type 2 diabetes, hypertension and established cardiovascular disease.

Participant Number:

By signing this form, I confirm that:

- I am 18 years of age or older.
- I have read, or had read to me, each page of this document, and understood its contents.
- All my questions were answered fully and to my satisfaction.
- I had enough time to think and decide whether to participate.
- I know that my participation is voluntary, and I can withdraw at any time without giving any reasons. I understand that leaving the study will not affect my ongoing medical care.
- I have informed the study doctor if I want to know about incidental findings or not.
- I will be given a copy of the signed and dated Information and Consent Form for my records.
- I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information.
- I agree that personnel acting on behalf of the sponsor, from health authorities, or from Ethics Committees can access my medical records.
- I agree to the collection, storage, processing, transfer, and use of my personal data and lab samples as explained in the above information.
- I consent to participate in this study.

**First and last name of
Study Participant**

(please print)

**Signature of Study
Participant**

Date

Study No: 1378-0041

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Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness to informed consent is required. If circumstances are not fulfilled leave this section blank.*

Name of Witness* to Participant's Signature (please print) _____	
Signature _____	Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Statement of Health Care Professional

I have explained the study and the terms of this Informed Consent Form to the study participant, and I answered all questions asked.

I acknowledge my responsibility for the care and well-being of the above study participant, to respect the rights and wishes of the person, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

**First and last name of Health
Care Professional**

(please print)

**Signature of Health Care
Professional**

Date